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Lead Counsel for Lead Plaintiff Carl Schwartz

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

TODD SCHUENEMAN, on behalf of himself and all others similarly situated,

Plaintiff,

vs.

ARENA PHARMACEUTICALS, INC., JACK LIEF, ROBERT E. HOFFMAN, DOMINIC P. BEHAN, WILLIAM R. SHANAHAN, and CHRISTY ANDERSON,

Defendants.

[Additional Captions on Following Pages]

Case No. 3:10-cv-01959-CAB

SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

WILLIAM SUTLIFF and JEAN SUTLIFF, on behalf of themselves and all others similarly situated, Plaintiff, vs. ARENA PHARMACEUTICALS, INC., JACK LIEF and WILLIAM SHANAHAN, JR. Defendants.	Case No. 3:10-cv-01961-CAB
WILLIAM PRATT, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. ARENA PHARMACEUTICALS, INC., JACK LIEF, ROBERT E. HOFFMAN, DOMINIC P. BEHAN, WILLIAM R. SHANAHAN, JR. and CHRISTY ANDERSON, Defendants.	Case No. 3:10-cv-01977-CAB
CRAIG RUBENSTEIN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. ARENA PHARMACEUTICALS, INC., JACK LIEF, ROBERT E. HOFFMAN, DOMINIC P. BEHAN, WILLIAM R. SHANAHAN, JR. and CHRISTY ANDERSON, Defendants.	Case No. 3:10-cv-01984-CAB

RODNEY VELASQUEZ, on behalf of himself and all others similarly situated, Plaintiff, vs. ARENA PHARMACEUTICALS, INC., JACK LIEF, ROBERT E. HOFFMAN, DOMINIC P. BEHAN, WILLIAM R. SHANAHAN, JR. and CHRISTY ANDERSON, Defendants.	Case No. 3:10-cv-02026-CAB
THONG VU, individually and on behalf of all others similarly situated, Plaintiff, vs. ARENA PHARMACEUTICALS, INC., JACK LIEF, ROBERT E. HOFFMAN, DOMINIC P. BEHAN, WILLIAM R. SHANAHAN, and CHRISTY ANDERSON, Defendants.	Case No. 3:10-cv-02086-CAB
ARIC D. JACOBSON, individually and on behalf of all others similarly situated, Plaintiff, vs. ARENA PHARMACEUTICALS, INC., JACK LIEF, ROBERT E. HOFFMAN, DOMINIC P. BEHAN, WILLIAM R. SHANAHAN, JR., and CHRISTY ANDERSON, Defendants.	Case No. 3:10-cv-02335-CAB

Lead Plaintiff Carl Schwartz, through Lead Counsel Kaplan Fox & Kilsheimer LLP, individually and on behalf of all other persons and entities similarly situated that purchased the securities of Arena Pharmaceuticals, Inc. ("Arena" or the "Company"), makes the following allegations, which are based upon the investigation conducted by Lead Plaintiff's counsel, which included, among other things, a review of the public statements made by defendants, Arena's filings with the United States Securities and Exchange Commission ("SEC"), transcripts of conference calls with investors and research analysts and a public meeting before the FDA's Endocrinology and Metabolic Advisory Committee ("Advisory Committee") on September 16, 2010, the Briefing Document prepared by Food and Drug Administration ("FDA") scientists for the Advisory Committee meeting (the "FDA Briefing Document"), press releases, analyst reports and media reports regarding Arena, and interviews with confidential informants.

I. NATURE OF THE CLAIMS

1. This is a securities class action brought under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder by the SEC, including Rule 10b-5, 17 C.F.R. § 240.10b-5, on behalf of purchasers of Arena securities between March 17, 2008 through January 27, 2011 (the "Class Period").

2. "Defendants" are the Company; Jack Lief ("Lief"), the Company's President, Chief Executive Officer and Chairman of the Company's board of directors; Robert E. Hoffman ("Hoffman"), the Company's Chief Financial Officer; Dominic P. Behan ("Behan"), the Company's Senior Vice President and Chief Scientific Officer and a member of the Company's board of directors; William R. Shanahan ("Shanahan"), the Company's Senior Vice President and Chief Medical Officer; and Christen "Christy" Anderson ("Anderson"), the Company's former Vice President of Lorcaserin Development.

3. Defendants violated the Exchange Act by making untrue statements of material facts, and/or omitting to state material facts necessary in order to make their statements, in light of

the circumstances under which they were made, not misleading about Arena's developmental new diet drug, lorcaserin.

4. Arena is a small biotechnology company and during the Class Period, Defendants primarily focused Arena's activities and resources on the research and development of lorcaserin. The Company did not sell any drug products.

5. During the Class Period, Arena had a Lorcaserin Team that conducted and/or supervised clinical and nonclinical tests required for approval by the FDA. According to Confidential Informant 1 ("CI 1"),[1] and Confidential Informant 2 ("CI 2"),[2] the Lorcaserin Team was led by Defendants Lief, Anderson, Shanahan and Behan, as well as other Arena senior management.

6. As members of the Lorcaserin Team, Defendants Lief, Shanahan, Anderson and Behan supervised the tests required for FDA approval of lorcaserin, including a key, long-term carcinogenicity study on rats (the "Rat Study") designed to approximate a lifetime of human use, and to assess risk to humans. Further, Defendants Lief, Shanahan, Anderson and Behan were privy to, and knowledgeable about, the protocols and results of the Rat Study and other studies of lorcaserin (*e.g.*, ¶¶ 8-15, 18), and attended meetings with the FDA at which the Rat Study and the FDA's concerns about the Rat Study's results and its significance to humans were discussed. (*E.g.*, ¶¶ 22, 24, 57, 85, 89.) As alleged below, Defendant Hoffman was aware of the Rat Study (*e.g.*, ¶¶ 17, 27, 29, 81, 91, 94).

7. By 2006, Defendants were conducting advanced human studies of lorcaserin (Phase 3 studies) and, at the same time, they were conducting other essential studies for lorcaserin's

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[1] CI 1 was a Senior Manager for Regulatory Affairs at Arena at the beginning of the Class Period through 2010, who handled correspondence with the FDA and prepared meeting packages, safety reports and carcinogenicity updates for the lorcaserin project.

[2] CI 2 was a Senior Director of Drug Safety Evaluation from October 2007 through 2009. CI 2 was responsible for monitoring the quality and standards used in animal studies of lorcaserin.

new drug application ("NDA") to the FDA, including nonclinical carcinogenicity and toxicity studies in animals, and the Rat Study to assess clinical risk to humans.

8. As members of the Lorcaserin Team, Defendants Shanahan and Anderson were tasked as the team leaders for lorcaserin's nonclinical and clinical studies. Shanahan and Anderson were responsible for collecting and analyzing all preclinical/animal and clinical data, including the Rat Study data, for lorcaserin's NDA, which data they discussed and shared with the other members of the Lorcaserin Team.

9. According to CI 1, the Rat Study data was collected by Bruce Ennis ("Ennis"), Arena's Associate Director and Head Toxicologist, who reported to Defendant Shanahan. Tina Leakakos, Arena's Associate Director of Drug Safety Evaluation, assisted Ennis. According to CI 1, Ennis received the data from the Rat Study from outside companies that ran the nonclinical trials. Ennis reported results to Shanahan who shared them with the other members of the Lorcaserin Team.

10. According to CI 1, Mark Brunswick ("Brunswick"), Arena's Senior Director of Regulatory Affairs during the Class Period (who reported to Defendant Lief), and Terri Heyward, Arena's Regulatory Manager, were the Regulatory Project Managers for lorcaserin.

11. Brunswick was responsible for sending and receiving communications with the FDA on behalf of Arena and senior management.

12. By February 2007, the results of the ongoing Rat Study indicated that lorcaserin caused mammary, brain, skin and nerve-sheath tumors, including lethal, malignant mammary and brain tumors. The results were unusual because the cancers were aggressive and occurred early in the Rat Study. The incidents of brain cancer were a concern because lorcaserin targets the central nervous system in the brain. The incidents of breast cancer were a concern because lorcaserin was a drug that would be marketed to people who are overweight and therefore have a higher risk of breast cancer. As members of the Lorcaserin Team, Defendants were aware of these results as they occurred.

13. According to Confidential Informant 3 ("CI 3"),[3] at a meeting in 2006 or 2007 with David Unett ("Unett"), who at the time was Arena's Senior Director, Receptor Pharmacology & Screening, Unett told CI 3 that "massive tumors in breast tissues in rats" were discovered. According to CI 3, Unett knew this because he had just left a meeting with the Lorcaserin Team at which the findings of the ongoing Rat Study were discussed.

14. According to CI 3, updates on lorcaserin were discussed several times during this meeting and in subsequent meetings. CI 3 and other Arena employees warned Unett that the "FDA is going to look into this" (tumor findings). Based on conversations with Unett, CI 3 believes that Arena executives withheld disclosing the tumor findings to the FDA "for several months, maybe longer." Further, CI 3 told Unett that the tumor findings "still have to be addressed to the FDA and investors," who were going to "take a poor view of where the data stands." According to CI 3, Unett concurred and responded that based on what he had learned at meetings with Arena executives, "the last thing they (Arena executives) want to do is raise awareness about them" (tumor findings).

15. On May 31, 2007, Defendants, through Brunswick (who reported to Lief), reported the unusual Rat Study results to the FDA, but not to the public. The FDA was very concerned about the Rat Study and, the FDA directed Defendants to prepare bi-monthly updates on the Rat Study's results as data became available for both mammary and brain tumors.

16. This direction by the FDA for bi-monthly updates was very unusual and was not part of the FDA's normal and customary process for new drug approval because interim results of ongoing rat studies are not typically provided to the FDA. In particular, the FDA was concerned about mammary and brain tumors that occurred during the Rat Study.

[3] CI 3 was a Senior Manager in Arena's Pharmacology and Screening Department Arena between 2000 and 2009.

17. In mid-2007, according to Confidential Informant 4 ("CI 4")[4], CI 4 was told by Barbara Koozer ("Koozer"), Arena's Purchasing Director, that Defendant Hoffman stated "they are trying to work on this cancer thing with the rats." Koozer told her team and CI 4 to "cross their fingers."

18. According to CI 2, in October 2007, CI 2 learned through conversations with Shanahan of tumor findings during the Rat Study and that Arena senior management had discussions with the FDA about the Rat Study and the cancer findings. According to CI 2, the findings of the ongoing Rat Study revealed unusual toxicology findings of tumors, and further that Lief, Anderson and Behan were aware of the tumor findings in the Rat Study.

19. On September 5, and November 9, 2007, and January 9, and March 10, 2008, on behalf of the Defendants, Brunswick submitted to the FDA bi-monthly updates on the ongoing Rat Study.

20. In or around March 2008, Brunswick, on behalf of Defendants, reported results from week 96 of the Rat Study to the FDA. The Rat Study results were alarming because: 1) at each update from week 55 to 96, the incidence and proportion of female rats with cancerous tumors (adenocarcinoma) increased at all doses; 2) a greater number of mammary-tumor-related deaths occurred early in the Rat Study; 3) mammary cancer metastasized to the lungs at all doses; and 4) and females were found with multiple cancerous masses at all doses.

21. The FDA was alarmed by these results and directed Arena to meet with the FDA in April 2008 to discuss the causes of mammary tumors in rats and the FDA's concern about its significance to humans.

22. On April 9, 2008, Defendants Shanahan, Anderson and Behan, as well as Brunswick, attended a meeting with the FDA in Silver Spring, Maryland. At this meeting, the FDA was surprised to learn that the Rat Study data from week 96 had changed mysteriously by week 104. Specifically, Defendants Shanahan, Anderson and Behan, as well as Brunswick, informed the FDA

[4] CI 4 was a Purchasing Assistant from July 2006 through February 2009.

that the Rat Study data indicated that the number of malignant mammary tumors ***decreased*** and the number of benign mammary tumors ***increased.*** The change in the Rat Study data was a significant concern for the FDA and no evidence was presented on behalf of Arena to explain this change, which reduced confidence in the data.

23. On May 16, 2008, Brunswick, on behalf of Defendants, submitted a bi-monthly update to the FDA.

24. According to CI 2, in mid-2008, Defendants Anderson, Shanahan and Behan, and Brunswick, as well as other Arena employees, met with FDA officials, including David Jacobson-Kram, Chair of the FDA Executive Carcinogenicity Assessment Committee, for approximately one hour at the FDA headquarters in Silver Spring, Maryland to discuss two topics – lorcaserin's clinical studies and the Rat Study.

25. On September 19, 2008, Brunswick, on behalf of Defendants, submitted a bi-monthly update to the FDA.

26. In or around October 2008, according to Confidential Informant 5 ("CI 5"),[5] CI 5 learned of the Rat Study and the tumor findings from conversations with Koozer.

27. In January 2009, CI 5 was instructed by Koozer that Lief and Hoffman gave the directive to all finance departments, including purchasing, to suspend any future purchases unless absolutely necessary. Based on discussions with Koozer and other Arena employees, CI 5 understood that management's directive to halt purchases was directly connected to growing uncertainty on whether lorcaserin would ever make it to market. For the first few months of 2009, CI 5 had "nothing to do." There was mounting concern within the Company that layoffs were forthcoming.

28. By February 2009, the Rat Study was completed and a draft of the final Rat Study report was sent to the FDA. The Rat Study found that breast tumors developed at all doses, and that lorcaserin caused brain tumors as well as many other malignant tumors.

[5] CI 5 was a Purchasing Manager for Arena from July 2002 through April 2009.

29. In April 2009, CI 5 was called into Hoffman's office along with 10-12 finance staff members and was informed by Hoffman that the staff members' respective positions at Arena were being eliminated. Based on discussions with other Arena employees, CI 5 understood that the layoffs were directly linked to management's concerns surrounding the future of lorcaserin.

30. On December 18, 2009, on behalf of Defendants, Brunswick submitted the lorcaserin NDA to the FDA, which included the final Rat Study data. Defendants could not demonstrate to the FDA that the Rat Study was irrelevant to humans. Moreover, the Rat Study data that Defendants submitted with the NDA changed yet again from the data first discussed with the FDA in April 2008, which further reduced confidence in the data.

31. Also in April 2010, Confidential Informant 6 ("CI 6"),[6] spoke with a former colleague who was working in Arena's Molecular Biology Department and who told CI 6 that there was "data which found cancer in the mice" and that "they (Arena management) did not want anyone else to know about it."

32. Defendants knew that the FDA was concerned about the results of the Rat Study and its applicability to humans. Indeed, in preparation for the September 16, 2010 public meeting with the FDA Advisory Committee, Arena hired an expert toxicologist to prepare slides and make a presentation addressing questions from the FDA concerning the relevance of the Rat Study results to humans.

33. Thus, by the beginning of the Class Period Defendants knew that the FDA was concerned about the results of the Rat Study. They also knew that there were material and unexplained changes in the mammary tumor updates which were presented to the FDA and that they were unable to demonstrate to the FDA that the Rat Study was irrelevant to humans. In short, they knew that the results of the Rat Study were material to the Advisory Committee and the FDA, and to investors.

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[6] CI 6 was a Research Associate in Arena's Molecular Biology Department at the beginning of the Class Period through 2009.

34. These were material facts that a reasonable investor would deem important in his or her decision whether to invest in Arena securities. But Defendants did not disclose these material facts to investors. Instead, Defendants repeatedly falsely represented that lorcaserin had an "excellent" and "remarkable" safety profile; that based on clinical and nonclinical studies and data, lorcaserin's "long-term safety" had been "demonstrated;" and that Defendants did not expect any "surprises" from the FDA.

35. As alleged below, Defendants' representations convinced analysts and investors that lorcaserin was safe and that the Company's application for approval by the FDA was "on track."

36. On September 14, 2010, investors began to learn the truth about lorcaserin when the FDA Briefing Document was released, publicly disclosing for the first time the adverse results from the Rat Study and the FDA's concerns about these results.

37. Analysts and investors were shocked by the disclosures of the results from the Rat Study – causing a massive collapse in the price of Arena securities. On September 14, 2010, Arena shares declined in price from a close on September 13, 2010 of $6.85 per share, to close at $4.13 per share, a decline of $2.72 per share or approximately 40% on heavy volume. On September 15, 2010, trading in Arena common stock was halted.

38. On September 16, 2010, a strong majority of the Advisory Committee (9 of 14 members) voted to not recommend approval of lorcaserin, in material part, because of concerns raised by the results of the Rat Study.

39. On September 17, 2010, trading in Arena shares resumed and the price of Arena's shares declined $1.75 per share to close at $1.99 per share, a decline of approximately 47% on heavy volume.

40. On October 23, 2010 the FDA sent Arena a "complete response letter" ("CRL") that informed Defendants that lorcaserin was not approvable and requested, among other things, the following information from Arena relating to the Rat Study: 1) a recount of the mammary tumors analyzed in the Rat Study updates to the FDA; and 2) further information concerning the relevance of the results to humans.

41. Even after the results from the Rat Study were disclosed and the FDA declined to approve Arena's NDA for lorcaserin, Defendants continued to mislead investors by failing to disclose additional material facts. On December 15, 2010, Defendants Lief, Shanahan, Anderson, and Behan, as well as Brunswick and other Arena senior management, met with the FDA. At this meeting, the FDA expressed its view that short-term studies of rats (duration of 6 months or less), would be insufficient to demonstrate that lorcaserin's tumor-causing effects were rat specific.

42. On December 22, 2010, on a conference call with investors Defendant Lief falsely represented that any further studies concerning applicability of the Rat Study to humans would be "short in duration."

43. On January 27, 2011, the end of the Class Period, Arena disclosed that the FDA recommended long-term studies of at least 12-months in duration to demonstrate that lorcaserin's mechanism was rat-specific.

44. Again, investors were shocked. On January 28, 2011, the price of Arena's common stock closed at $1.63 per share, a decline of $0.37 per share or approximately 19% from the closing price on January 27, 2011, on heavy volume.

II. JURISDICTION AND VENUE

45. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act.

46. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §§ 1391(b) and (c). Substantial acts in furtherance of the wrongs alleged and/or their effects have occurred within this District and Arena maintains its headquarters in San Diego, California.

47. In connection with the facts and omissions alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. THE PARTIES

48. Lead Plaintiff purchased Arena securities as detailed in the certification previously filed with the Court and was damaged thereby.

49. Defendant Arena is incorporated in Delaware and has executive offices in San Diego, California. The Company's common stock trades on the NASDAQ under the symbol "ARNA." Arena purports to be a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing drugs for cardiovascular, central nervous system, inflammatory and metabolic diseases. During the Class Period, the Company did not sell any products.

50. During the Class Period, Arena, a small company, focused on the development of lorcaserin. Arena's 2009 annual report filed with the SEC on March 16, 2010 on Form 10-K (the "2009 10-K") stated that "we are focusing our activities and resources on our lorcaserin program." According to the 2009 10-K, approximately 95% and 86% of Arena's total external clinical and preclinical study fees and expenses related to lorcaserin in 2009 and 2008, respectively.

51. Defendant Lief was, at all relevant times, the Company's President and Chief Executive Officer, and Chairman of the Company's board of directors. Lief is a co-founder of the Company. During the Class Period, Lief made false statements in the Company's quarterly and annual reports filed with the SEC, in certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX Certifications") that were filed with the SEC, and in conference calls with investors and research analysts.

52. Defendant Hoffman was, at all relevant times, the Company's Vice President, Finance and Chief Financial Officer. During the Class Period, Hoffman made false statements in the Company's quarterly reports and in SOX Certifications that were filed with the SEC. Hoffman left Arena in February 2011 and later in 2011 returned to the Company as CFO.

53. Defendant Behan was, at all relevant times, the Company's Senior Vice President and Chief Scientific Officer and a member of the Company's board of directors. Behan is a co-founder of the Company. During the Class Period, Behan made false statements in the Company's

annual reports filed with the SEC and made false statements in conference calls with investors and research analysts.

54. Defendant Shanahan was, at all relevant times, the Company's Senior Vice President and Chief Medical Officer. During the Class Period, Shanahan made false statements in conference calls with investors and research analysts.

55. Defendant Anderson was the Company's Vice President of Lorcaserin Development during the Class Period and left Arena after the Class Period. During the Class Period, Anderson made false statements in conference calls with investors and research analysts.

56. Defendants Lief, Shanahan, Behan, Anderson and Hoffman are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Arena's press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's press releases and filings with the SEC alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material, non-public information available to them but not to the public, each of the Individual Defendants knew that the adverse material facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were materially false and misleading at that time.

57. Defendants Lief, Shanahan, Anderson and Behan attended meetings with the FDA concerning lorcaserin, including meetings at which the Rat Study and the FDA's concerns about its findings were discussed.

58. During the Class Period, each of the Individual Defendants knew of the Rat Study results, received and/or had access to data concerning lorcaserin, including the results of the Rat Study, and made false statements about lorcaserin's safety.

59. During the Class Period, none of the Individual Defendants purchased Arena common stock on the open market and Lief, Shanahan, Behan and Hoffman were subject to at least one "lock-up" agreement that prevented them from selling shares of Arena common stock.

60. During the Class Period, Defendants caused Arena to sell stock at artificially inflated prices, raising over $150 million for Arena. The sales were suspicious as they occurred after or around the same time as Defendants learned of material negative facts, and/or were timed to occur just before a partial disclosure of their wrongful conduct that caused Arena common stock to decline. For example, on August 6, 2010, Defendants caused Arena to sell approximately 8.9 million shares at approximately $6.70 per share for proceeds of approximately $60 million. This sale was suspicious because it occurred after Defendants learned about all of the material negative facts alleged above concerning the Rat Study, and just weeks before Defendants' meeting with the Advisory Committee. As alleged above, the disclosures on September 14 and 17, 2010 caused Arena's stock to decline to $1.99 per share at the close of trading on September 17, 2010.

IV. BACKGROUND AND BASIS OF DEFENDANTS' LIABILITY

A. Background on Arena's Development of Lorcaserin.

1. Arena's Animal (Non or Pre-Clinical) and Human (Clinical) Studies of Lorcaserin.

61. Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss. Lorcaserin is described by Arena as "a novel single agent that represents the first in a new class of selective serotonin 2C receptor agonists. The serotonin 2C receptor is located in areas of the brain involved in the control of appetite and metabolism, such as the hypothalamus. Stimulation of this receptor is strongly associated with feeding behavior and satiety." Because lorcaserin's mechanism affected the central nervous system in the brain, any signal of brain tumors would be a red flag of a safety risk.

62. Arena has been developing lorcaserin since at least 2003. To market lorcaserin, Arena needs approval from the FDA. Approval by the FDA of a new drug requires a new drug

sponsor to submit data demonstrating the drug's safety and efficacy based on nonclinical animal studies and clinical trials on humans. Human clinical trials are referred to as phases 1, 2, and 3. Phase 1 trials are mainly aimed at determining if the metabolic and pharmacologic actions of the drug in humans are safe enough to proceed to Phase 2 studies. Phase 2 studies are controlled clinical studies that involve a limited population infected with the disease the drug proposes to treat. Phase 3 studies usually involve many more people than Phase 2 studies and are intended to gather additional information on the drug's efficacy and safety that will be used in evaluating its overall risks and benefits. Nonclinical animal studies include long-term studies on animals of a drug's toxicity and carcinogenicity.

63. Between 2006 and 2009, Arena concurrently conducted nonclinical animal studies, (including the Rat Study) and human studies, including two "pivotal" Phase 3 trials - BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management) - all of which were intended to be submitted with the lorcaserin NDA.

64. BLOOM started in September 2006 and was completed in February 2009. BLOSSOM was conducted between January 2008 and July 2009.

2. Lorcaserin's Safety Was Critical to the FDA and Investors.

65. As with all new drugs, a drug sponsor must demonstrate the drug's safety. Safety with respect to diet drugs was highly important because prior FDA-approved diet drugs, including Fen-Phen, were removed from the market because of serious adverse side effects after it was shown that they cause heart-valve disease (valvulopathy).

66. Fen-Phen, like lorcaserin, was a "serotonin agonist", and affects the brain and central nervous system in similar ways. As such, it was important for Arena to demonstrate that lorcaserin did not cause negative side effects. Indeed, in February 2008, just before the beginning of the Class Period, Defendant Lief acknowledged that focus was on "safety, safety, safety, safety … and then safety."

67. Further, lorcaserin's safety profile was of paramount importance to investors. Vivus and Orexigen, competitors of Arena, were developing competing weight-loss drugs (qnexa and contrave, respectively) and certain clinical studies for these drugs showed potential adverse side effects, like birth defects and cardiovascular risks.

68. Accordingly, Defendants represented that lorcaserin was different from the drugs being developed by Vivus and Orexigen because, according to Defendants, lorcaserin was purportedly ***both*** safe and effective.

3. The Individual Defendants knew of the Rat Study results, and received and/or had access to data concerning lorcaserin, including the results of the Rat Study.

69. As noted above, Arena was required to conduct a long-term study of potential carcinogenesis relating to lorcaserin, including the Rat Study. Carcinogenicity studies, like the Rat Study, are highly relevant to humans because they are designed to approximate results of lifetime use of a drug in humans and to detect tumor risks in humans.

70. When safety margins are absent or uncertain in a carcinogenicity study, it is critical that a drug sponsor demonstrate that the drug's mechanism or tumorigenic mode of action is not relevant to humans.

71. Pursuant to FDA protocols, during a carcinogenicity study, rats are observed on a daily basis for signs of departure from normal activity, morbidity and mortality. If tumors develop, the time of onset, location, dimensions, appearance and progression are recorded.

B. Defendants' Fraudulent Conduct.

1. Arena's Rat Study Reveals to Defendants Alarming Findings.

72. By February 2007, Defendants learned that the Rat Study showed lorcaserin caused tumors in rats, including malignant mammary (breast) tumors in both male and female rats, malignant astrocytoma (brain cancer), squamous carcinomas of the subcutis (skin cancer), malignant schwannomas (cancer of connective tissue surrounding nerves or nerve sheath tissue), liver and thyroid.

73. According to CI 3, at a meeting with Unett, Unett told CI 3 that "massive tumors in breast tissues in rats" were discovered. According to CI 3, Unett knew this because he had just left a meeting with the Lorcaserin Team that included Defendant Behan at which the findings of the ongoing Rat Study were discussed.

74. According to CI 3, updates on lorcaserin were discussed several times during this meeting and in subsequent meetings. CI 3 and other team members warned Unett that the "FDA is going to look into this" (cancer findings). Based on conversations with Unett, CI 3 believes that Arena executives withheld disclosing the cancer findings to the FDA "for several months, maybe longer." Further, CI 3 told Unett that even if the findings were not relevant to humans, "it still has to be addressed to the FDA and investors," who were going to "take a poor view of where the data stands." According to CI 3, Unett concurred and responded that based on what he had learned at meetings with Arena executives, "the last thing they (Arena executives) want to do is raise awareness about them" (cancer findings).

2. Defendants Inform the FDA of Lorcaserin's Risks and the FDA Directs Defendants to Provide Bi-Monthly Updates on the Results of the Rat Study.

75. On May 31, 2007, Defendants submitted a safety report informing the FDA of increased mortality of female rats due to breast cancers and tumors (mammary adenocarcinoma and fibroadenoma) at all doses of lorcaserin by week 55 of the ongoing Rat Study. Additionally, Defendants described a higher incidence of brain cancer (astrocytoma).

76. Mammary tumors were of particular concern to the FDA because potential lorcaserin users – overweight and obese women – were a group that was already at high risk for breast cancer. Brain tumors were a concern because lorcaserin's mechanism affects the central nervous system in the brain.

77. The high incidence of mortality and palpable tumors in female rats observed during the course of the Rat Study, as well as the incidents of brain cancer, prompted the FDA to direct that Defendants provide bi-monthly updates to the FDA regarding the incidence of observed tumors in the Rat Study, including survival and tumor incidence.

78. The cancer observed in the Rat Study was unusual because cancer occurred very early in the Rat Study and the cancers observed were aggressive. As Defendant Lief later admitted, Arena's bi-monthly updates to the FDA were highly unusual and not part of the normal process with the FDA.

79. Defendants' bi-monthly updates to the FDA were unusual because interim results of rat studies are not typically provided to the FDA. The bi-monthly updates were reviewed by the FDA and the findings were periodically discussed with the FDA's Executive Carcinogenicity Assessment Committee (eCAC). The FDA considered the Rat Study's findings relevant to humans. According to CI 1, at least 10 carcinogenicity updates were sent by Defendants to the FDA.

80. The FDA's request for bi-monthly updates put the Defendants on notice and was a red flag that the FDA had concerns about the findings of breast, brain and other tumors in the Rat Study and that they were relevant to humans.

81. In mid-2007, CI 4 was told by Koozer that Defendant Hoffman stated "they are trying to work on this cancer thing with the rats." Koozer told her team and CI 4 to "cross their fingers."

82. In October 2007, CI 2 learned through conversations with Shanahan of tumor findings during the Rat Study and that Arena senior management had discussions with the FDA about the Rat Study. According to CI 2, the findings of the ongoing Rat Study revealed unusual toxicology findings of tumors.

3. The Ongoing Rat Study Results Reveal Increases in Tumors and Cancer.

83. By March 2008, week 96 of the Rat Study had been reached. The number of deaths and the incidence of malignant and benign mammary tumors ***increased*** at all doses of lorcaserin in each bi-monthly update. This was reported to the FDA by Defendants. The increase in cancer found in the ongoing Rat Study concerned the FDA and the FDA directed that Defendants meet with the FDA.

84. As alleged above, by the beginning of the Class Period (March 17, 2008), each of the Individual Defendants knew about the Rat Study's negative findings and that the FDA was concerned that the results were relevant to humans.

85. On April 9, 2008, Defendants Shanahan, Behan and Anderson, as well as Brunswick, met with the FDA to discuss the tumor findings in rats and the potential safety implications for the ongoing clinical studies and the Rat Study's relevance to humans.

86. At that meeting, Defendants informed the FDA that the week 96 data previously reported to the FDA had changed to show a ***decline*** in the total number of malignant mammary tumors and an ***increase*** in benign mammary tumors. The sudden shift was highly unusual, and was imbalanced, which reduced confidence in the reliability of the data.

87. At the April 2008 meeting, Defendants did not provide data to the FDA to explain the mysterious and sudden shift in favor of lorcaserin.

88. The FDA conditionally permitted Defendants to continue clinical studies because incidents of tumors and tumor risk would be monitored in clinical studies and Defendants did not have certain data from the Rat Study at that time. The FDA requested a draft report of the Rat Study as soon it was available.

89. According to CI 2, in mid-2008, Defendants Anderson, Shanahan and Behan, and Brunswick as well as other Arena employees, met with FDA officials at the FDA headquarters in Silver Spring, Maryland to discuss the lorcaserin NDA at which one of two topics on the agenda was the ongoing Rat Study.

90. In or around October 2008, according to CI 5, CI 5 learned of the Rat Study and its negative findings from conversations with Koozer**.**

91. In January 2009, CI 5 was instructed by Koozer that Lief and Hoffman gave the directive to all finance departments, including purchasing, to suspend any future purchases unless absolutely necessary. Based on discussions with Koozer and other Arena employees, CI 5 believed that management's directive to halt purchases was directly connected to growing uncertainty on whether lorcaserin would ever make it to market.

92. For the first few months on 2009, CI 5 had "nothing to do." There was mounting concern within the Company that layoffs were forthcoming.

93. On February 3, 2009, with the Rat Study completed, Brunswick, on behalf of Defendants, submitted a draft of the final Rat Study to the FDA. The Rat Study found mammary tumors occurred at all doses, and that lorcaserin causes brain and other cancers.

94. In April 2009, CI 5 was called into Hoffman's office along with 10-12 finance staff and was informed by Hoffman that the staff members' respective positions at Arena were being eliminated. Based on discussions with other Arena employees, CI 5 believed that the layoffs were directly linked to management's concerns surrounding the future of lorcaserin.

95. Around the same time, while knowing of the Rat Study and its relevance to humans and the FDA's concerns about them, or at least ignoring all of these risks with deliberate recklessness, Defendants caused Arena to sell millions of dollars in Arena common stock at artificially inflated prices. On April 14, 2009, Defendants caused Arena to sell approximately 5.7 million Arena shares at an artificially inflated price ($2.61 per share) for proceeds of $15 million. On July 8, 2009, Defendants caused Arena to sell 12.5 million Arena shares at an artificially inflated price ($4.17 per share) for proceeds of approximately $ 52.1 million.

96. On August 9, 2009, Defendants Shanahan, Anderson, and Behan, and Brunswick conducted a pre-NDA meeting with the FDA to discuss lorcaserin.

97. On a November 10, 2009 conference call with investors and research analysts, Defendants were specifically asked to identify any FDA concerns with lorcaserin.

98. Despite knowing of the negative results of the Rat Study, and that the FDA was concerned about the results and their applicability to humans, Defendant Shanahan lied to investors, stating "at the present time we don't see safety signal[s] to pursue. . . ." Again, Defendants failed to disclose the negative results of the Rat Study, and that the FDA was concerned about the results and their applicability to humans.

99. On December 18, 2009, Brunswick, on behalf of Arena, submitted the NDA for lorcaserin. The NDA included the final Rat Study data.

100. The final Rat Study data that Brunswick submitted on behalf of Defendants was *further* revised from the data that Defendants reported to the FDA in April 2008 to show an increase in benign tumors and a decrease in malignant tumors, and there were gross errors in the pathology reports. Rat tissue samples that contained tumors were identified as normal, which reduced confidence in the data.

101. Defendants did not submit data that demonstrated that the results of the Rat Study were irrelevant to humans. No safety margin was identified for the mammary tumors and the safety margin for brain tumors was uncertain. The final Rat Study data that Defendants submitted to the FDA showed that tumors in female rats occurred at ***all*** doses and increased multiple tumor types in male rats, and that tumors occurred early and were very aggressive, leading to premature deaths. Defendants had no plausible explanation for these results.

4. Defendants Mislead Investors Prior to the September 16, 2010 Advisory Committee Meeting.

102. After Defendants filed the lorcaserin NDA, investors repeatedly asked Defendants about the status of the NDA application and about any FDA concerns with lorcaserin. Despite knowing of the material, negative results of the Rat Study, that the FDA was concerned about the results and their applicability to humans, and that the final Rat Study update materially changed from prior updates, Defendants lied to investors by failing to disclose these material facts.

103. On March 8, 2010, while knowing of the Rat Study and its relevance to humans and the FDA's concerns about such, or at least ignoring all of these risks with deliberate recklessness, Defendants caused Arena to sell approximately 8.3 million Arena shares at an artificially inflated price ($2.96 per share) for proceeds of approximately $24.5 million.

104. In April 2010, CI 6 spoke with a former colleague who was working in Arena's Molecular Biology Department and was told that there was "data which found cancer in the mice" and that "they (Arena management) did not want anyone else to know about it."

105. Defendants' repeated lies concerning lorcaserin's safety misled investors in Arena stock, including sophisticated research analysts. On May 7, 2010, a Cowen & Co. analyst observed that lorcaserin's "**Modest Efficacy Plus Clean Safety Carves Out Niche**".

106. On June 2, 2010, Arena disclosed that it had been notified that the FDA Advisory Committee would meet publicly on September 16, 2010 to consider whether to recommend lorcaserin's approval to the FDA.

107. Defendant Lief represented that "[w]e are focused on obtaining the FDA's approval of lorcaserin, and have been preparing for this anticipated advisory committee meeting," but again failed to disclose the material, negative results of the Rat Study and the FDA's concerns about these results.

108. Defendants knew that the Rat Study and its relevance to humans and the FDA's concerns about the Rat Study were issues for the Advisory Committee. Notably, Arena retained Dr. Gary Williams ("Dr. Williams"), a New York Medical College Pathologist with a focus on the mechanisms of carcinogenesis and the metabolic and genetic effects of chemical carcinogenesis, to present a slide presentation to the Advisory Committee, a fact indicating that Defendants knew that the results of the Rat Study were materially important to the FDA and would be important to the Advisory Committee's and FDA's consideration of Arena's NDA for lorcaserin.

109. On June 2, 2010, an Oppenheimer analyst stated "we do not see negative read-through for the lorcaserin NDA … we believe lorcaserin's clean safety profile in trials to date, including minimal cardiovascular side effects, should sway the [Advisory Committee] panel to recommend approval. . . ."

110. Defendants knew that the FDA continued to have concerns about the mysterious changes to the Rat Study results. At the request of the FDA's Division of Metabolism and Endocrinology Products, on June 7 through 11, 2010, the FDA's Division of Scientific Inspections inspected Arena and a facility where nonclinical studies for the Rat Study were conducted. The inspections concerned, in part, the change in tumor classification in the Rat Study and the quality

and integrity of the data compiled in the Rat Study. In June 2010, a Form 483 was issued to Arena regarding the inspection.

111. As late as August 3, 2010, Defendant Shanahan represented in a conference call with investors and research analysts that he did not expect any "surprises" at the September 16 FDA Advisory Committee meeting. But, internally, Defendants knew about the negative results of the Rat Study and the FDA's concern about those results. Indeed, Defendants were preparing for the September 16, 2010 Advisory Committee meeting by preparing slides and statements to address the negative results of the Rat Study.

112. On August 5, 2010, while knowing of the Rat Study and its relevance to humans and the FDA's concerns about such, and knowing that Defendants and their expert Dr. Williams were preparing to give a presentation concerning the Rat Study, or at least ignoring these risks with deliberate recklessness, Defendants caused Arena to sell 9 million shares of Arena common stock at an artificially inflated price ($6.70 per share) for proceeds of $60 million.

113. As late as August 2010, based on Defendants' false representations, analysts continued to believe that lorcaserin was safe: "lorcaserin appears relatively well positioned with two years of controlled safety data, no clear adverse safety signal, and a robust clinical trial design" (J.P. Morgan); "We believe that lorcaserin's profile is fundamentally approvable." (Jefferies); and "We expect Additional Upside on a Positive Lorcaserin AdCom Mtg. . . . The company reported that no new issues have emerged ahead of the 9/16 FDA AdCom meeting for lorcaserin. . . . **Safety is lorcaserin's defining characteristic, in our view**." (Oppenheimer) (emphasis added).

5. The Truth about Lorcaserin Begins to be Revealed.

114. On September 14, 2010, the FDA Briefing Document and the negative results from the Rat Study and the FDA's concern about the results were publicly disclosed for the first time, causing Arena's stock price to decline.

115. On September 14, 2010, the price of Arena shares declined from a close on September 13, 2010 of $6.85 per share, to close at $4.13 per share, a decline of $2.72 per share or approximately 40% on heavy volume.

116. Investors and analysts, without exception, were shocked and surprised:

- September 14, 2010 J.P. Morgan *ALERT*: "**The biggest surprise is a preclinical cancer signal.** We (and investors we've spoken with this morning) were caught off guard by the question relating to lorcaserin-related tumors in rats. In the FDA's question alone, the agency specifically notes that the neoplasms involve breast, brain, peripheral nerve, skin, and subcutis. . . ." (emphasis in original);

- September 14, 2010 Cowen Analyst Report: "Quick Take: Rat Carcinogenicity Data A Surprise In Briefing Docs . . . . The documents were disappointing in that they showed a major disagreement between Arena and the FDA on the interpretation of preclinical rat carcinogenicity findings that had not previously been disclosed. We believe the fact that the FDA believes that lorcaserin increases the risk for malignant breast tumors in rats reduces the likelihood that lorcaserin will receive a positive panel recommendation on Thursday. . . .";

- September 14, 2010 Jefferies Analyst Report: "The biggest surprise in the briefing documents is the finding of preclinical cancers";

- September 14, 2010 Oppenheimer Analyst Report –"**We see the FDA's rejection of ARNA's explanation of pre-clinical cancers in rats as a significant concern"** (emphasis in original);

- September 15, 2010 Canaccord Analyst Report: "**Cancer risk in the briefing document was unforeseen; presents another challenge for lorcaserin, especially since it is a new chemical entity"** (emphasis added); and

- September 15, 2010 Summer Street Analyst Report: "Yesterday **we were completely blindsided by preclinical carcinogenicity data from the two year lorcaserin animal study**. . . . Most importantly, we do not believe Arena will be able to produce preclinical data and/or design a post-approval trial/registry to rule out a breast cancer risk" (emphasis added).

117. On September 16, 2010, the Advisory Committee met and heard statements from FDA scientist Dr. Fred Alavi, who authored a report on the Rat Study that was part of the FDA Briefing Document, and Dr. Williams, on behalf of Arena, who gave a presentation concerning the Rat Study.

118. After hearing statements and presentations from Arena, FDA scientists, and others, the Advisory Committee voted 9-5 against recommending approval of lorcaserin, in material part, because of safety concerns raised by the Rat Study and their relevance to humans.

119. On September 17, 2010, Lief and Shanahan participated in a conference call with investors and research analysts to discuss the Advisory Committee meeting and Lief made the following admissions:

> **Karen Jay** - *JPMorgan - Analyst*
>
> I had a question about the pre-clinical cancer signals. I was wondering when -- I guess you're aware of them pretty early and the cancer, you had potentially underestimated the FDA's concern on that topic.
>
> **Jack Lief** - *Arena Pharmaceuticals Inc. - President & CEO*
>
> Well, what we can say, as we stated in our presentation yesterday, is that ***when we learned of the data, we promptly discussed it with the FDA***.
>
> * * *
>
> **Bill Tanner** - *Lazard Capital Markets – Analyst*
>
> And just -- and I don't know if you were there, I'm sure you would have been debriefed. How much of an in depth discussion was it? How much of it was back and forth? You may not wish to comment on it, but was there any kind of inkling, any kind of thought that perhaps the FDA reviewers would have been in agreement? Or are they just cursorily looking at your data, making a cursory decision to proceed without any real hard analytical processes being done?
>
> **Jack Lief** - *Arena Pharmaceuticals Inc. - President & CEO*
> Yes, you know we can't provide more details on that at this time. But I appreciate your question.

(Emphasis added).

6. The FDA Rejects Arena's NDA.

120. On October 23, 2010, Arena disclosed that it received the CRL from the FDA that indicated that the FDA completed its review of the NDA and the FDA could not approve Arena's NDA "in its present form." The CRL, according to Arena, outlined the reasons for the FDA's decision, including the following:

> The non-clinical issues identified by the FDA included diagnostic ***uncertainty in the classification of mammary masses in female rats, unresolved exposure-response***

> ***relationship for lorcaserin-emergent mammary adenocarcinoma, and unidentified mode of action and unclear safety margin for lorcaserin-emergent brain astrocytoma***.

(Emphasis added).

121. Further, according to Defendants, the FDA requested that Defendants provide the following evidence to address the FDA's concern that the Rat Study was relevant to humans – concerns that the Defendants knew about by the beginning of the Class Period: (1) provide a valid explanation for the mysterious reclassification of tumors between week 96 and week 104 of the Rat Study ("provide a detailed accounting of all slides prepared from female rats that contributed to mammary tumor incidence data in each update to the FDA and to the final study report; in consultation with the FDA, identify an independent pathologist or group of pathologists to re-adjudicate all mammary and lung tissues (neoplastic and nonneoplastic lesions) from all female rats"); and (2) show that the Rat Study is not relevant to humans ("demonstrate that the apparent increase in aggressiveness of adenocarcinoma in rats administered lorcaserin is reasonably irrelevant to human risk assessment," and "provide additional data/information regarding the distribution of lorcaserin to the central nervous system in animals and human subjects that would clarify or provide a better estimate of astrocytoma exposure margins").

122. The FDA further stated in the CRL that "in the event evidence cannot be provided to alleviate concern regarding clinical [human] relevance of the tumor findings in rats, additional clinical studies may be required to obtain a more robust assessment of lorcaserin's benefit-risk profile." (Alteration added).

123. On October 25, 2010, Lief, Hoffman, Shanahan and Behan conducted a conference call with investors and research analysts concerning the CRL and Lief made the following statements:

> **Bill Tanner** - *Lazard Capital Markets – Analyst*
>
> Can you help us understand a little bit the first sentence on the fourth paragraph about detailed accounting of slides prepared? Is there a snafu here, or what's the gist of that? … It says, provide a detailed accounting of all slides prepared from female

rats [contribute] to [mammary] tumor incidence, and each update to FDA in the final report. Is there an accounting issue with the slides or with the data?

Jack Lief - *Arena Pharmaceuticals - President & CEO*

As the FDA indicated in their briefing document, what they were concerned about were the changes between the initial readings by a single veterinary pathologist as part of the normal process, and then the final peer-reviewed, adjudicated diagnoses for each of these slides. ***We, at the FDA's request, got into an out-of-process type of procedure whereby we updated, every two months, the Agency with the results…*** some of these diagnoses changed from when the final peer review process with -- I believe that included three veterinary pathologists reviewed the slides and came to a consensus view on them. So that's how that changed. Normally, the only data submitted to the Agency would be the final peer reviewed data. . . .

[Question:] I was wondering if the panel of three vet pathologists that you used to review the mammary tumors at the end of the study were also retained to go back and review the earlier slides. Did they indeed come up with different diagnoses than the earlier reports?

Jack Lief - *Arena Pharmaceuticals - President & CEO*

The process was that we had a single pathologist ma[k]e the initial reads as the study was ongoing. At the request of the FDA we provided these data every two months as the study was unfolding. And then the normal process is you never submit those data. Everyone gets together and makes a final reading on these tissues, and then that's what gets accounted for in the study report. So it's just the change from an initial reading from one pathologist. And so that's the process.

Steve Byrne - *Banc of America – Analyst*

Okay, and just an overall question about the rat study. ***Almost half of the female rats in the control study had mammary tumors, and that just seems to be outside the historical range. Do you have any hypotheses as to why there was such prevalence of rat tumors in the females***?

Jack Lief - *Arena Pharmaceuticals - President & CEO*

Yes, we don't. It was slightly -- I believe the upper range on the lab was around 40%, and we were, I think, around 43% or 44% in the control group. So outside the range, very high FDN. But no, ***we don't have an explanation for that. . . .***

Jim Birchenough - *Barclays Capital – Analyst*

I just wanted to follow up on the pre-clinical data and the request by FDA for the slides. How difficult is it to distinguish between adenocarcinoma and fibroid

> adenoma? ***And I ask the question because, between week 96 and week 104 it seemed like there were several animals that were reclassified, or at least that was the question that FDA raised in their briefing documents***. And I just wanted confirmation that in animals that were reclassified as fibroadenoma from adeno, they had no evidence of lung metastases. And then I have a follow-up.
>
> **Jack Lief** - *Arena Pharmaceuticals - President & CEO*
>
> We'll have to review all those data, but we have the data, and we will review it. . . .

(Emphasis added).

7. Defendants Mislead Investors Concerning the "End of Review" Meeting with the FDA.

124. On December 15, 2010, Defendants Lief, Shanahan, Behan, and Anderson, as well as Brunswick and other Arena senior management, met with the FDA in Silver Spring, Maryland. At this meeting the FDA expressed its view that short-term studies were insufficient to demonstrate that lorcaserin's tumor-causing mechanism was specific to rats, indicating that studies of at least 6 months or longer would be required.

125. On December 22, 2010, Arena issued a press release disclosing that Defendants completed the "end-of-review" meeting with the FDA for lorcaserin that stated, in part, the following:

> Based on guidance we have received from the agency, we are executing several activities and expect to resubmit the lorcaserin NDA by the end of 2011. . . . The end-of-review meeting with the FDA included a discussion of the FDA's position on issues identified in the CRL and Arena's plan to respond.

126. Also on December 22, 2010, Defendants conducted a conference call with investors and research analysts to discuss the "end-of-review" meeting with the FDA, and Lief and Anderson made the following statements:

> **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP of Lorcaserin Development*
>
> The FDA has asked that we demonstrate the mechanism by which lorcaserin causes mammary tumors in rats and that this mechanism is reasonably irrelevant to human risk. . . . To address this issue, we have initiated nonclinical studies to provide the requested evidence to the agency.

> **Carol Werther** - *Summer Street Research - Analyst*
> So the duration of the trial is pretty short then?
>
> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President and CEO*
> Yes.

127. On January 27, 2011, after the close of trading, in a report filed with the SEC on Form 8-K, Arena disclosed that the FDA required the Company to perform additional long-term studies to demonstrate lorcaserin was safe for humans:

> [T]he FDA requested that we consider performing a separate 12-month study in female rats that would test whether transient prolactin elevation mediated by short-term exposure to lorcaserin can result in mammary tumors in rats. . . .

128. On January 28, 2011, Arena shares declined from a closing price on January 27, 2011 of $2 per share, to close at $1.63 per share, a decline of $0.37 per share or approximately 19%, on heavier than usual volume.

D. Defendants' Materially False and Misleading Statements and Material Omissions.

129. Defendants' statements were untrue statements of material facts and/or omitted to state material facts necessary in order to make their statements in light of the circumstances under which they were made, not misleading, because Defendants intentionally, or with deliberate recklessness, failed to disclose the following to investors:

(i) that by February 2007, Defendants Lief, Shanahan, Behan and Anderson learned that the findings of the Rat Study included mammary and brain tumors (¶¶ 12, 72);

(ii) that on May 31, 2007, Defendants alerted the FDA of the adverse findings from the Rat Study and the FDA instructed that Arena provide updates every two months to the FDA on the Rat Study's breast and brain tumors results, an unusual request for interim results that is not part of the normal FDA process for development of new drugs (¶¶ 15, 16, 75-79);

(iii) that starting in May 2007, Arena provided bi-monthly updates to the FDA on the Rat Study and in September 2007 Defendants began sending formal bi-monthly updates to the FDA (¶¶ 15, 19, 23, 25, 77);

(iv) that in March 2008, Defendants sent the Rat Study's results from week 96 that revealed tumors increased at all doses. The FDA was alarmed by these findings because the results of the Rat Study between weeks 55 and 96 showed an increase in tumors at all doses. The FDA directed Defendants to meet with the FDA in April 2008 to discuss the Rat Study and its relevance to humans (¶¶ 20-22, 83);

(v) that on April 9, 2008, Defendants Shanahan, Anderson and Behan met with the FDA to discuss the Rat Study and its relevance to humans and Defendants told the FDA that the week 104 data from the Rat Study changed. Specifically, the number of benign mammary tumors ***increased*** and the number of malignant tumors ***decreased***, which reduced confidence in the Rat Study data. Defendants did not provide any documentation to explain the mysterious and sudden shift (¶¶ 22, 86, 87); and

(vi) that in mid-2008, Defendants Shanahan, Anderson, Behan, as well as Brunswick met with the FDA and discussed the ongoing Rat Study results (¶¶ 24, 89);

(vii) that on February 3, 2009, the Rat Study was completed and a draft of the report was sent to the FDA. By early 2009, Defendants Lief and Hoffman, aware of the Rat Study, began to implement budget cuts, such as the termination of employment of Arena employees, due to the uncertainty of lorcaserin's NDA (¶¶ 28-29, 91-94);

(viii) that in December 2009, at the time Defendants submitted lorcaserin's NDA along with the final Rat Study, Defendants were not able to demonstrate to the FDA that the Rat Study results were irrelevant to humans, and could not explain the tumor reclassification between the week 96 data and the week 104 data of the Rat Study (¶¶ 30, 99-101); and

(ix) that at the "end-of-review" meeting on December 15, 2010 with the FDA as part of a resubmission of lorcaserin's NDA, Defendants learned that the FDA was interested in additional long-term (longer than 6 months) studies of lorcaserin's effects on rats. (¶¶ 41-42, 124-28).

130. The Class Period begins on March 17, 2008 when Defendants caused Arena to issue a press release that represented that lorcaserin passed a key safety test demonstrating lorcaserin's cardiovascular safety:

> **Arena Pharmaceuticals' Lorcaserin for Obesity Passes Major Safety Milestone**
>
> *- Month-12 Independent Echocardiographic Data Safety Monitoring Board Review Strengthens Lorcaserin's Emerging Cardiovascular Safety Profile -*
>
> SAN DIEGO, March 17 /PRNewswire-FirstCall/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that following a planned review by an independent Echocardiographic Data Safety Monitoring Board (EDSMB) it is continuing BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), a pivotal trial evaluating the efficacy and safety of lorcaserin hydrochloride for the treatment of obesity. . . . This critical milestone assessing month-12 echocardiographic data strongly supports lorcaserin's cardiovascular safety profile. We believe that this exposure duration, even under a conservative interpretation of the literature, would have been sufficient to observe a fenfluramine [Fen-Phen] like effect on heart valves if present.

131. The representation that Defendants collected data that "strongly supports" lorcaserin's safety profile was false and misleading because Defendants knew of the material facts in ¶ 129(i)-(iii) and intentionally or with deliberate recklessness failed to disclose them to investors.

132. On May 12, 2008, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended March 31, 2008. The May 12, 2008 10-Q was signed by Lief and Hoffman, and stated, in part, the following:

> In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. . . .

133. Lief and Hoffman's representations that Defendants "completed long-term preclinical toxicity studies for lorcaserin," that "short-term carcinogenicity and toxicity studies have been completed" and that the carcinogenicity studies were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(v) and intentionally or with deliberate recklessness failed to disclose them to investors.

134. The May 12, 2008 10-Q included SOX Certifications signed by Lief and Hoffman that represented that they each reviewed the 10-Q and they each represented that it "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report. . . ."

135. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(v) and intentionally or with deliberate recklessness failed to disclose them to investors in the May 12, 2008 10-Q.

136. On August 11, 2008, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended June 30, 2008. The August 11, 2008 10-Q was signed by Lief and Hoffman and, stated, in part, the following:

> In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. . . .
>
> Our most advanced drug candidates, including lorcaserin … have not completed all preclinical studies … for efficacy and safety that are required for FDA approval.

137. Lief and Hoffman's representations that Defendants "completed long-term preclinical toxicity studies for lorcaserin," that "short-term carcinogenicity and toxicity studies have been completed" and that carcinogenicity studies for lorcaserin were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors.

138. The August 11, 2008 10-Q included SOX Certifications signed by Lief and Hoffman similar to the SOX Certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

139. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors in the August 11, 2008 10-Q.

140. On November 7, 2008, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended September 30, 2008. The 10-Q was signed by Lief and Hoffman and, stated, in part, the following:

> In addition to successfully completing clinical trials, in order to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These studies in animals are required to help determine the potential risk that drug candidates may be toxic or cause cancer in humans. The preclinical assessment of carcinogenic potential includes short-term in vitro and in vivo studies to look for chromosomal damage. Short-term carcinogenicity and toxicity studies have been completed for all of our clinical-stage programs. To date, we have only completed long-term preclinical toxicity studies for lorcaserin, and we have not completed carcinogenicity studies for lorcaserin or any of our other clinical-stage programs. . . .
>
> Our most advanced drug candidates, including lorcaserin … have not completed all preclinical studies … for efficacy and safety that are required for FDA approval.

141. Lief and Hoffman's representation that Defendants "completed long-term preclinical toxicity studies for lorcaserin," that "short-term carcinogenicity and toxicity studies have been completed" and that the carcinogenicity studies for lorcaserin were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors.

142. The November 7, 2008 10-Q included SOX Certifications signed by Lief and Hoffman similar to the SOX Certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

143. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vi) and intentionally or with deliberate recklessness failed to disclose them to investors in the November 7, 2008 10-Q.

144. On March 12, 2009, Hoffman, Lief, Behan and Shanahan participated in a conference call with investors and research analysts, and Lief made the following statements:

> **Phil Nadeau** - *Cowen & Co. - Analyst*
>
> Good evening, thanks for taking my question. Jack, my first one is to you, in your prepared remarks you made the comment that you folks are getting increasingly confident on lorcaserin's potential based on the blinded data that you're saying. I was wondering if you could elaborate on that comment, what in particular is giving you confiden[ce] and maybe even more importantly, what have you really learned since the R&D day, if anything, that has made your confidence increase?
>
> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President, CEO*
>
> Well, the confidence is not just based on the blinded data, of course, the confidence is based on the Phase II data, the Phase I data, the preclinical studies that was done, all the animal studies that have been completed, as well as how the studies are recruiting, have recruited, the retention in those studies, and that sort of thing. So since the December date, of course, we've finished the BLOOM study, and so that gives us a lot more confidence that we're unlikely to find some surprises that we're not already aware of. Keep in mind the data is still blinded, so I don't know who's on drug and who's on placebo, so we might be surprised when we unblind the data. But it looks like we're seeing such things that we absolutely would expect to see.

145. Lief's representations were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

146. Also on March 12, 2009, Defendant Shanahan represented that "[a]nimal studies" provided "a lot of visibility on our safety associated with lorcaserin."

147. Defendant Shanahan's representations were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

148. On March 16, 2009, Defendants caused Arena to file its annual report for the year ended December 31, 2008 with the SEC on Form 10-K ("2008 10-K"). The 2008 10-K was signed by Lief, Hoffman and Behan and stated, in part, the following:

> Based on preclinical studies and clinical trial data to date, we believe that lorcaserin is unlikely to cause serotonin-mediated valvulopathy or other cardiovascular side effects.

***

> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates. . . .
>
> ***
>
> In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.
>
> ***
>
> Our most advanced drug candidates, including lorcaserin, have not completed all preclinical studies … for efficacy and safety that are required for FDA approval.

149. Lief, Hoffman and Behan's representation that "[b]ased on preclinical studies and clinical trial data to date, we believe that lorcaserin is unlikely to cause serotonin-mediated valvulopathy or other cardiovascular side effects," and representations that "preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

150. The 2008 10-K included SOX Certifications signed by Lief and Hoffman similar to the certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

151. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors in the 2008 10-K.

152. On March 23, 2009, Defendants caused Arena to file a prospectus with the SEC on Form 424B2 (the "March 23 Prospectus"). The March 23 Prospectus related to a registration statement on Form S-3 that Arena filed with the SEC, using a "shelf" registration process and stated

that Arena "from time to time [will] offer to sell up to 25,000,000 shares of our common stock at prices and on terms described in one or more supplements to this prospectus." The March 23 Prospectus incorporated by reference the false statements in the 2008 10-K delineated above in ¶¶ 148, 150.

153. On March 30, 2009, Defendants caused Arena to issue a press release that stated, in part, the following:

> Arena Pharmaceuticals Announces Positive Lorcaserin Pivotal Phase 3 Obesity Trial Results: Meets All Primary Efficacy and Safety Endpoints
>
> **Lorcaserin Very Well Tolerated Throughout Two-Year Study…**
>
> Safety and Tolerability Profile
> Lorcaserin was generally very well tolerated. The most frequent adverse events reported in Year 1 and their rates for lorcaserin and placebo patients, respectively, were as follows: headache (18.0% vs. 11.0%), upper respiratory tract infection (14.8% vs. 11.9%), nasopharyngitis (13.4% vs. 12.0%), sinusitis (7.2% vs. 8.2%) and nausea (7.5% vs. 5.4%). The most frequent adverse events reported in Year 2 and their rates for lorcaserin and placebo patients, respectively, were as follows: upper respiratory tract infection (14.5% vs. 16.1%), nasopharyngitis (16.4% vs. 12.6%), sinusitis (8.6% vs. 6.9%), arthralgia (6.6% vs. 6.2%) and influenza (6.6% vs. 6.0%). In patients crossing over from lorcaserin to placebo after Year 1, the rates of these Year 2 adverse events were: 11.0%, 13.8%, 10.6%, 6.0% and 4.9%, respectively.
>
> Adverse events of depression, anxiety and suicidal ideation were infrequent and reported at a similar rate in each treatment group, and no seizures were reported. Serious adverse events occurred with similar frequency in each group throughout the trial without apparent relationship to lorcaserin. One death occurred during the trial, which was a patient in the placebo arm.

154. Defendants' representation that lorcaserin was "very well tolerated" based on data collected throughout a two-year study was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

155. Also on March 30, 2009, Lief, Shanahan, Behan and Anderson participated in a conference call with investors and research analysts, and Defendant Shanahan made the following statements:

> [B]ased on earlier data and Lorcaserin-selected mechanism, the topline data has not indicated any significant safety concerns….

> I believe the BLOSSOM data will support our findings to date and allow us to submit a robust database to the FDA for its evaluation….
>
> ***
>
> We primarily look at safety and that's what -- again, we're getting support for the excellent safety profile of the drug.

156. Shanahan's representations concerning lorcaserin's mechanism was safe for use in humans, that "topline data has not indicated any significant safety concerns," and that Defendants were getting support for lorcaserin's "excellent safety profile" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

157. Also on March 30, 2009, Defendant Lief made the following representation in response to an analyst's question:

> **Alan Carr** - *Needham & Company - Analyst*
> [C]an you tell me a bit more about what you think the FDA is looking for in the year two data? . . .
>
> **Jack Lief** - *Arena Pharmaceuticals - President and CEO*
> We also know that there is no increase in any heart valve disease and we're not aware of any excess in other areas as well. So we are really thrilled that we have such an effective as well as safe compound. . . .
>
> ***
>
> We don't believe that there's any numerical disadvantage in any of these important risk factors. And as you will see when the full data set is presented, our drug will be very safe, well-tolerated.
>
> I think there's a lot of information in the press release. I think over the two-year period of time, as I said, more people lose more weight in a safer fashion on Lorcaserin. The heart valves, there is a slight increase in placebo versus drug.
>
> So clearly there is no signal there. . . . And so I'm really happy that we have such a safe drug without the CNS or cardiovascular side effects that have plagued other drugs potentially in the past.

158. Defendant Lief's answer to research analyst Alan Carr's question "[c]an you tell me what you think the FDA is looking for in the year two data?" was materially false and misleading

because Lief failed to disclose the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors. Further, Lief's representations that the "full data set" showed lorcaserin was "very safe", and that lorcaserin was a safe drug without CNS, or central nervous system, side effects, were false and misleading because Defendants knew of ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

159. On April 14, 2009, Defendants caused Arena to file a Form 424B5 with the SEC (the "April 14 Prospectus Supplement"). The April 14 Prospectus Supplement related to Arena's offering 5,745,591 shares of Arena common stock to Azimuth Opportunity Ltd. ("Azimuth") pursuant to a Common Stock Purchase Agreement, dated March 23, 2009, between Arena and Azimuth, at a price of approximately $2.61 per share, for a total purchase price for the shares of $15.0 million. The April 14 Prospectus Supplement incorporated by reference the false statements in the 2008 10-K and the March 30, 2009 press release delineated above in ¶¶ 148, 150, 153.

160. On May 11, 2009, Defendants caused Arena to issue a press release in which it disclosed its financial results for the quarter ended March 31, 2009. The press release stated, in part, the following:

> Treatment with lorcaserin was generally very well tolerated. Lorcaserin treatment for up to two years was not associated with evidence of heart valve damage; rates for the development of echocardiographic FDA-defined valvulopathy were similar to placebo throughout the study.

161. Defendants' representation that lorcaserin was "well tolerated" and that the two-year data showed that lorcaserin was safe were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

162. On May 11, 2009, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended March 31, 2009. The 10-Q was signed by Lief and Hoffman and stated, in part, the following:

> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy

> have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.
>
> ***
>
> In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.
>
> ***
>
> Our most advanced drug candidates, including lorcaserin, have not completed all preclinical studies … for efficacy and safety that are required for FDA approval.

163. Lief and Hoffman's representations that "long-term safety and efficacy" had been demonstrated in clinical trials of lorcaserin and that preclinical, animal studies were ongoing were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

164. The May 11, 2009 10-Q included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

165. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

166. Also, on May 11, 2009, Defendants participated in a conference call with investors and research analysts, and Lief made the following statements:

> Based on results from the BLOOM trial meeting the FDA's efficacy criteria, and coupled with a strong tolerability profile, that includes no signal of FDA Valvulopathy at any time point over the two-year treatment period, we believe that lorcaserin is approvable for weight management, both here in the US, and eventually in Europe as well . . . .
>
> First, patients on lorcaserin in the BLOOM trial generally tolerated the drug very well. The only adverse event that exceeded placebo by 5% or greater was headache. We know from BLOOM and previous trials, that headaches associated with lorcaserin are typically mild and transient. We think that this tolerability profile will provide physicians with the confidence to use lorcaserin as a first line therapy for the majority of their patients…

167. Lief's representations that lorcaserin was safe and had a strong tolerability profile were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

168. On June 6, 2009, Defendants caused Arena to issue a press release that stated, in part, that as "[p]reviously announced BLOOM data demonstrated that lorcaserin … was very well tolerated. . . ."

169. Defendants' representation was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

170. On July 8, 2009, Arena issued 12,500,000 shares of its common stock at a public offering price of $4.17 per share pursuant to a prospectus supplement and registration statement filed with the SEC on Form 424B5 on July 8, 2009 (the "July 8 Prospectus Supplement"). The common stock offering was made pursuant to a shelf registration statement Arena filed with the SEC on November 25, 2008, which became effective on December 3, 2008 (File No. 333-155660) and was signed by Lief, Hoffman and Behan. The July 8 Prospectus Supplement incorporated by reference the false statements in the 2008 10-K, the May 11, 2009 10-Q and the March 30, 2009 press release delineated above in ¶¶ 148, 150, 153, 162, 164.

171. On August 3, 2009, Defendants caused Arena to issue a press release in which Lief stated, in part, the following:

> Based on its emerging efficacy, safety and tolerability profile, lorcaserin has the potential to be an important new treatment option for patients needing to better manage their weight and improve their overall health.

172. Lief's representation that lorcaserin had an emerging "safety and tolerability profile" was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

173. On August 3, 2009, Defendants participated in a conference call with investors and research analysts, and Lief made the following statement:

> We believe that Lorcaserin's complete efficacy, safety and tolerability profile will position the drug candidate as an ideal new option to help manage excess body weight and its associated risks. . . . This compelling safety and efficacy profile will differentiate Lorcaserin from currently-available therapies and others in late-stage development.

174. Lief's representations that lorcaserin's safety profile was "complete" and "compelling," and that lorcaserin's safety profile differentiated it from drugs being developed by its competitors (Orexigen and Vivus), were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

175. Also on August 3, 2009, Defendant Anderson made the following representations:

> **Alan Carr** - *Needham & Company - Analyst*
> Are there any other gating studies, preclinical or clinical, that are still needed at the FDA? Is the -- that last abuse potential trial, is that the last of them?
>
> **Anderson:**
> The (inaudible) study pretty much finished up that package that we are planning to submit to the FDA as our initial NDA, so we will have no additional studies that we'll be submitting in the initial NDA once we complete that study report.

176. Defendant Anderson's representations regarding the completed clinical and preclinical studies were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

177. On August 3, 2009, Defendants caused Arena to file a registration statement on Form S-3 with the SEC for the sale of up to 28 million shares of Arena common stock that was signed by Lief, Hoffman and Behan that incorporated by reference the false statements in the 2008 10-K, the May 11, 2009 10-Q and the March 30, 2009 press release delineated above in ¶¶ 148, 150, 153, 162, 164.

178. On August 7, 2009, Defendants caused Arena to file its quarterly report with the SEC on Form 10-Q for the period ended June 30, 2009. The 10-Q was signed by Lief and Hoffman, and stated, in part, the following:

> Lorcaserin was very well tolerated, did not result in increased risk of depression and was not associated with development of cardiac valvular insufficiency.

***

> In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.

***

> In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.

***

> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

179. Lief and Hoffman's representation that the "long-term safety and efficacy" of lorcaserin was demonstrated was false and misleading because by August 7, 2009, Defendants' preclinical studies, including the Rat Study, on lorcaserin were completed, and Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

180. The August 7, 2009 10-Q included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q alleged above in ¶ 134.

181. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors in the August 7, 2009 10-Q.

182. On September 18, 2009, Defendants caused Arena to issue a press release that stated, in part the following, and quoted Defendant Lief:

> Lorcaserin was very well tolerated and was not associated with depression or suicidal ideation. The integrated echocardiographic data set from BLOSSOM and

> BLOOM rules out a risk of valvulopathy in lorcaserin patients according to criteria requested by the FDA. Treatment with lorcaserin also resulted in significant improvements as compared to placebo in multiple secondary endpoints associated with cardiovascular risk. . . . "History has taught us that the marriage of efficacy and safety is of critical importance in treating patients. Neither is sufficient without the other. With its excellent safety and tolerability profile, we expect lorcaserin to change the way primary care doctors treat the broad cross-section of overweight and obese patients with pharmacotherapy," said Jack Lief, Arena's President and Chief Executive Officer.

183. Lief's representation that lorcaserin had an "excellent safety profile" was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

184. The September 18, 2009 press release quoted Shanahan as stating the following:

> These results support lorcaserin's potential to meet the need for a safe, effective and well-tolerated weight loss medication. There are only two drugs that are approved by the FDA for long-term treatment, and new mechanistic and better tolerated approaches could greatly improve the treatment of patients who are obese or significantly overweight.

185. Shanahan's representation that lorcaserin's "mechanism" was safe and well-tolerated was false and misleading because Shanahan knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

186. On September 18, 2009, Lief, Behan, Shanahan and Anderson participated in a conference call with investors and research analysts, and Lief, Behan and Anderson made the following statements regarding lorcaserin's safety:

> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President, CEO*
> We showed that lorcaserin has an excellent safety and tolerability profile….
>
> **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP Clinical Development*
> Lorcaserin met all of BLOSSOM's primary efficacy and safety endpoints and helped patients achieve significant weight loss with a remarkable tolerability and safety profile. . . . We are pleased to deliver a single agent that achieves rapid and clinically meaningful efficacy concomitant with remarkable safety and tolerability…. Lorcaserin is further differentiated from approved drugs for weight management and those in development [qnexa and contrive] by its excellent safety and tolerability profile.
>
> ***

Dominic Behan - *Arena Pharmaceuticals, Inc. - CSO*
We have shown that it is possible to engineer an efficacious weight management drug candidate with an excellent safety and tolerability profile…. Safety and tolerability are the foundation for compliance in the broad population of obese and overweight patients.

***

Jack Lief - *Arena Pharmaceuticals, Inc. - President, CEO*
As we've seen, lorcaserin side effects are not really meaningfully different than placebo, but patients lose twice as much weight on lorcaserin as on placebo. So we think that it's a compelling story, this marriage of efficacy, safety and tolerability.

***

Dominic Behan - *Arena Pharmaceuticals, Inc. - CSO*
[T]hat's the true unmet need in the real world which is the marriage, as Jack said, between the efficacy and the tolerability and the safety. I mean, you can't have one without the other in order to address this issue in the broad diverse obese population. It's very important that you have all of those attributes in your drug. And we have clearly shown that lorcaserin's profile meets that unmet need in the real world.

***

Jack Lief - *Arena Pharmaceuticals, Inc. - President, CEO*
[b]ecause we've tested our drug for two years I think most physicians will be comfortable with long-term use of our compound.

***

Jack Lief - *Arena Pharmaceuticals, Inc. - President, CEO*
it's a very effective drug, very safe. . . .

Dominic Behan - *Arena Pharmaceuticals, Inc. - CSO*
In order to have an effective viable commercial drug applicable to the broad diverse population, this marriage that Jack talked about of efficacy, tolerability and safety is absolutely critical, absolutely critical. And we have captured that profile very nicely with lorcaserin.

187. Lief, Anderson and Behan's representations that lorcaserin was safe and had an "excellent safety and tolerability profile," and that lorcaserin's safety profile differentiated it from other weight-loss drugs in development by Arena's competitors, were false and misleading because they knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

188. Also on September 18, 2009, Lief, Anderson and Behan made the following statements regarding lorcaserin's "mechanism":

> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President, CEO*
> [lorcaserin] is a game changer in the weight management area. . . . If you look at drugs to treat hypertension, physicians have numerous choices of mechanisms to use. In weight management there are only two and the side affects actually limit the usefulness of these drugs. So I think physicians really need another choice, another mechanism, a new mechanism.
>
> ***
>
> **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP Clinical Development*
> Again, you've got to let us save some of the thunder here for our scientific meeting that's upcoming. I'll just reiterate that we did rule out the risk of valvulopathy the way we agreed to with the FDA. And I think this just supports both our hypothesis for the mechanism of the drug and supports the safety of the drug….
>
> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President, CEO*
> Keep in mind that the receptor, the target that lorcaserin goes after is not found in the heart basically. So the 2C receptor is largely central in the brain. And so that's very consistent, the mechanism is very consistent with the clinical as well as pre-clinical experience that we know for lorcaserin. So we're excited to be able to support all of these hypotheses regarding having a selective drug that only addresses this hypothalamic target.

189. Lief and Behan's representations regarding lorcaserin's "mechanism" and Defendants' "pre-clinical experience" with lorcaserin were false and misleading because they knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

190. Also on September 18, 2009, Behan and Anderson made the following statements regarding the data concerning lorcaserin's safety:

> **Dominic Behan** - *Arena Pharmaceuticals, Inc. - CSO*
> As you can see from the data, we believe that lorcaserin is a game changer.
>
> ***
>
> **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP Clinical Development*
> You know, we've, I think, put together pretty much all of the data that we now need for this NDA. We have favorable results on everything that we've compiled so far.

191. Behan and Anderson's representations regarding the data collected for the lorcaserin NDA were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

192. On October 12, 2009, Defendants caused Arena to file a press release in which Shanahan is quoted as stating the following:

> "The positive results from our Phase 3 pivotal program highlight lorcaserin's potential to provide physicians with a treatment option that combines three important attributes - efficacy, safety and tolerability - critical to broad applicability in the majority of their patients to help manage weight and improve cardiometabolic health," stated William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer.

193. Shanahan's representations concerning lorcaserin's safety were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

194. On October 27, 2009, Defendants caused Arena to issue a press release in which Lief and Shanahan are quoted as making the following statements:

> William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer, stated, "Based on lorcaserin's safety and efficacy profile, we expect primary care physicians to find lorcaserin an attractive first-line therapy for weight management…."
>
> ***
>
> "Our team at Arena has worked diligently to discover and develop a novel treatment for weight management that delivers the combination of efficacy, safety and tolerability. . . ," said Jack Lief, Arena's President and Chief Executive Officer….

195. Lief and Shanahan's representations that lorcaserin was safe were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

196. On October 30, 2009, Defendants caused Arena to file a report with the SEC on Form 8-K that stated, in part, that lorcaserin was "very well tolerated."

197. This statement was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

198. On November 9, 2009, Defendants caused Arena to issue a press release, and caused Arena to file its quarterly report for the quarter ended September 30, 2009 with the SEC on Form 10-Q, which signed by Lief and Hoffman, that stated, in part, the following:

> Lorcaserin was very well tolerated and no excess depression or suicidal ideation was observed with lorcaserin treatment. The incidence of new FDA-defined valvulopathy from the integrated echocardiographic data set from BLOSSOM and BLOOM did not differ from placebo.

199. These representations that lorcaserin was safe were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

200. Also, Lief and Hoffman made the following representations in the November 9, 2009 10-Q:

> Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. . . .
>
> In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.
>
> ***
>
> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

201. Lief and Hoffman's representations that Defendants demonstrated lorcaserin's "long-term safety" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

202. The November 9, 2009 10-Q included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

203. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors in the November 9, 2009 10-Q.

204. On November 10, 2009, Defendants conducted a conference call with investors and research analysts, and Lief made the following statements concerning the data collected concerning lorcaserin:

> **Jack Lief** - *Arena Pharmaceuticals - Chairman, CEO, President*
> Let me begin by telling you that our Lorcaserin program remains on track… I am pleased to report at this time we have all of the data in hand that will be included in the new drug application that we are planning to submit to the FDA next month.
>
> ***
>
> Two-year data support Lorcaserin's long-term safety profile.

205. Also on November 10, 2009, Lief and Anderson made the following statements concerning lorcaserin's safety:

> **Christen Anderson** - *Arena Pharmaceuticals - VP, Clinical Development*
> Lorcaserin's overall profile of medically meaningful efficacy combined with excellent safety and tolerability was received with support and enthusiasm from the physicians in attendance at Obesity 2009. . . .
>
> **Jack Lief** - *Arena Pharmaceuticals - Chairman, CEO, President*
> Lorcaserin has a unique competitive profile and is differentiated from currently approved treatments for weight management and those in development by a number of important characteristics. Lorcaserin has the right combination of meaningful efficacy with a safety profile that is similar to placebo and avoids increased blood pressure and heart rate, depression, suicidal ideation and cardiac toxicity. Lorcaserin has demonstrated an outstanding tolerability profile reflected by the low incidence of withdrawals due to adverse events.

206. Also on November 10, 2009, Shanahan made the following statements concerning Defendants' meeting with the FDA concerning the lorcaserin NDA and lorcaserin's safety:

> [A]t the present time we don't see safety signal to pursue, so we are going to down evaluate our data, file the NDA and then have discussions with the FDA after that.

207. The representations alleged in ¶¶ 204-06 were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(vii) and intentionally or with deliberate recklessness failed to disclose them to investors.

208. On November 12, 2009, Defendants caused Arena to file a prospectus with the SEC on Form 424B3 relating to the resale, from time to time, of up to 28,000,000 shares of Arena common stock by Deerfield Management Company, L.P. (and affiliated entities) that incorporated by reference the false statements in the 2008 10-K, the May 11, August 7 and November 9, 2009

10-Qs, and the March 30, September 18 and October 27, 2009 press releases delineated above in ¶¶ 148, 150, 153, 162, 164, 178, 180, 182, 184, 194, 198, 200, 202.

209. On December 22, 2009, Defendants caused Arena to issue a press release that stated, in part, the following:

> William R. Shanahan, M.D., Arena's Vice President and Chief Medical Officer, stated, "… Based on the robust data package we submitted to the FDA, lorcaserin has the potential to meet this need, offering patients the opportunity to achieve sustainable weight loss in a well-tolerated manner and improve their cardiometabolic health and quality of life. . . ."
>
> The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years and showed that lorcaserin consistently produced significant weight loss with excellent safety and tolerability.

210. Shanahan's representations that a "robust data package" showed lorcaserin produced weight loss with "excellent safety and tolerability" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

211. On February 24, 2010, Defendants caused Arena to issue a press release that quoted Defendant Lief as stating the following:

> "The FDA's acceptance of the lorcaserin NDA is a significant milestone towards our goal of providing physicians and their patients with a new mechanistic approach to achieve sustainable weight loss in a well-tolerated manner," said Jack Lief, Arena's President and Chief Executive Officer. "We look forward to working with the FDA to facilitate a thoughtful and efficient review of the lorcaserin NDA."
>
> The NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase 3 clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant weight loss with excellent safety and tolerability.

212. Lief's representations that based on the "data package" submitted with the NDA, which included the negative Rat Study results, lorcaserin's mechanism was safe, were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

213. On February 26, 2010, Defendants caused Arena to issue a press release that stated, in part, the following:

> Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) announced today that the US Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of October 22, 2010, for the review of the lorcaserin New Drug Application (NDA). The acceptance of the lorcaserin NDA filing confirms that the application is sufficiently complete to permit a substantive review, and the PDUFA date is the goal date for the FDA to complete its review of the NDA...
>
> Jack Lief, Arena's President and Chief Executive Officer, stated, "With an October PDUFA date for the lorcaserin NDA, we are another step closer to our goal of improving the treatment of obesity. We believe that lorcaserin, if approved, will be well positioned as first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner."

214. Lief's representation that lorcaserin was "well-tolerated" was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

215. On March 8, 2010, Defendants caused Arena to file a prospectus supplement and accompanying prospectus pursuant to which Arena offered 8,278,432 shares of Arena common stock to Azimuth, pursuant to a Common Stock Purchase Agreement, dated March 23, 2009, between Arena and Azimuth, at a price of approximately $2.96 per share, for a total purchase price of $24.5 million (the "March 8 Prospectus Supplement").

216. The March 8 Prospectus Supplement incorporated by reference the false statements in the 2008 10-K, the May 11, August 7, and November 9, 2009 10-Qs and the March 30, September 18, October 27, and December 22, 2009, February 24, and February 26, 2010 press releases delineated above in ¶¶ 148, 150, 153, 162, 164, 178, 180, 182, 184, 194, 198, 200, 202, 209, 211, 213.

217. On March 12, 2010, Defendants caused Arena to issue a press release that quoted Defendant Lief as stating the following:

> "We are pleased with the timely execution and significant progress made in our lorcaserin program," stated Jack Lief, Arena's President and Chief Executive Officer. "As we continue efforts to reach a commercial agreement for lorcaserin, we are building a strong foundation for a successful launch upon potential approval."

218. Lief's representations were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

219. On March 12, 2010, Defendants participated in a conference call with investors and research analysts, and Lief made the following statements:

> A couple of weeks ago we announced that the FDA accepted our NDA for filing and assigned October 22 as the PDUFA date. We are pleased to be on track as we move through an exciting year for Arena.
>
> ***
>
> Lorcaserin holds significant potential to re-energize and expand the weight management category based on its unique combination of safety, efficacy and tolerability.
>
> ***
>
> The FDA has said that there is sufficient data to review lorcaserin on its merits. We have also had discussions and meetings around that. So while there can never be any guarantees on anything these days, we are reasonably confident, I'm reasonably confident that the FDA will review our current package as submitted in a scientific fashion.
>
> ***
>
> Lorcaserin was so well tolerated, and we don't see any safety signals that require special attention right now.

220. Lief's representations that lorcaserin was safe, that he was "confident" in the data submitted to the FDA, and that Defendants did not "see any safety signals" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

221. Also on March 12, 2010, Lief made the following statements concerning Defendants discussions with the FDA:

> **Thomas Wei** - *Jefferies - Analyst*
> I had a question actually on the regulatory process so far for lorcaserin. Can you share with us any of the questions or issues that were raised in the 74-day letter from the FDA that you must have just gotten from them?

> **Jack Lief** - *Arena Pharmaceuticals - Chairman, CEO & President*
> Well, we typically do not go into the details of FDA correspondence. Having said that, we are confident that we have the ability to work with the FDA in the future during their review of the NDA, and I think we will be able to satisfy if there are any questions that they might have in the future.

222. Lief's representations concerning Arena's correspondence with the FDA, and that he was "confident" that Defendants would be able to satisfy any questions were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

223. Also on March 12, 2010, Behan made the following statements concerning Defendants' preparation for the FDA Advisory Committee meeting:

> **Terence Flynn** - *Lazard Capital Markets - Analyst*
> Okay and just a follow-up question. There has been a lot of focus obviously on a potential panel. I'm just wondering what you guys are doing to prepare for that and how you potentially plan to frame the discussion around the risk benefit of the drug at that potential panel if it does occur?
>
> **Dominic Behan**
> Well, again, [while] we have not got any specific data or communication regarding if a panel will occur, we are assuming one will, and we are preparing intensely for it. So this is quite a process. There's [sic] thousands of slides that will need to be prepared, that will be needed to be appropriately brought up to address questions almost instantaneously. So we have a team focused on that process.

(Alteration added).

224. Behan's representations were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

225. On March 16, 2010, Defendants caused Arena to file the 2009 10-K. The 2009 10-K was signed by Lief, Hoffman and Behan, and stated, in part, the following:

> Lorcaserin was very well tolerated, did not result in increased risk of depression or suicidal ideation and was not associated with the development of cardiac valvular insufficiency.
>
> ***

> Safety and Tolerability Profile
>
> Treatment with lorcaserin was very well tolerated, resulting in very few adverse events with greater frequency than the placebo group.
>
> ***
>
> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

226. Lief, Behan and Hoffman's representation that lorcaserin was safe, and that Defendants demonstrated lorcaserin's "long-term safety" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

227. The 2009 10-K included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

228. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors in the 2009 10-K.

229. On May 7, 2010, Defendants caused Arena to file its quarterly report for the quarter ended March 31, 2010 with the SEC on Form 10-Q. The May 7, 2010 was signed by Lief and Hoffman and stated, in part, the following:

> Preclinical studies include experiments performed in test tubes, in animals, or in cells or tissues from humans or animals. These studies include all drug studies except those conducted in human subjects, and may occur before or after initiation of clinical trials for a particular compound. . . .
>
> In addition to successfully completing clinical trials, to conduct long-term clinical trials and gain regulatory approval to commercialize drug candidates, regulatory authorities require that all drug candidates complete short- and long-term preclinical toxicity and carcinogenicity studies. These preclinical, animal studies are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans.
>
> ***

> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

230. Lief and Hoffman's representation that Defendants demonstrated lorcaserin's "long-term safety" was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

231. The May 7, 2010 10-Q included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

232. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors in the May 7, 2010 10-Q.

233. On June 2, 2010, Defendants caused Arena to issue a press release that quoted Defendant Lief as stating the following:

> "We are focused on obtaining the FDA's approval of lorcaserin, and have been preparing for this anticipated advisory committee meeting," said Jack Lief, Arena's President and Chief Executive Officer. "With its unique combination of safety, tolerability and efficacy, we believe that lorcaserin, if approved, has the potential to serve as first-line therapy to help patients achieve sustainable weight loss in a well-tolerated manner."

234. Lief's representation that lorcaserin was safe was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them.

235. On June 22, 2010, Defendants caused Arena to file a prospectus with the SEC on Form 424B3 that incorporated by reference the false statements in the 2009 10-K, the May 7, 2010 10-Q and the February 26, 2010 press release delineated above in ¶¶ 213, 225, 227, 229, 231.

236. On July 14, 2010, Arena issued a press release that stated, in part, that "[a]mong the most frequent adverse events reported with lorcaserin were headache (18.0% vs. 11.0%, lorcaserin vs. placebo); dizziness (8.2% vs. 3.8%); and nausea (7.5% vs. 5.4%). The rates of serious adverse

events were similar in both treatment groups. The rates of depression and the incidence of anxiety and suicidal thoughts were low in both treatment groups. Lorcaserin caused no significant increase compared to placebo in the incidence of new cardiac valvulopathy."

237. Defendants' representation that lorcaserin was safe, was false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

238. Also on August 3, 2010, Defendants participated a conference call with investors and research analysts, and Lief made the following statements:

> **Jack Lief** - *Arena Pharmaceuticals - Chairman, President, CEO*
> We have recently announced a number of important milestones in the lorcaserin program, and we're right on track with our plans. . . . Our primary objective at this time is to obtain FDA approval for lorcaserin. We are preparing for our advisory committee meeting, tentatively scheduled for September 16, and look forward to our October 22 PDUFA date. We have always stated that safety is of paramount importance to the FDA, and that the right profile of efficacy, safety, and tolerability is essential for a weight-management drug. . . .
>
> **Jack Lief** - *Arena Pharmaceuticals - Chairman, President, CEO*
> In conclusion, we believe that lorcaserin's unique profile, safety, efficacy, and tolerability as demonstrated in our pivotal program, has the potential to advance the management of obesity. We are pleased with the recent execution of critical milestones and look forward to continuing interaction with the FDA to complete its review of the lorcaserin application.

239. Lief's representation that lorcaserin was safe and that Defendants "always stated that safety is of paramount importance to the FDA" were false and misleading because Lief knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them.

240. Also on August 3, 2010, Shanahan, Lief and Anderson made the following representations concerning Defendants discussions with the FDA:

> **Phil Nadeau** - *Cowen & Co. - Analyst*
> Okay. Can you maybe give us some idea of what you think the issues could be? Or where you are focusing your preparation?
>
> **Bill Shanahan** - *Arena Pharmaceuticals - SVP, Chief Medical Officer*
> Well, we're not expecting any surprises associated with the panel. Obviously we will present our view of lorcaserin, and the FDA will present their view. I think the views

will overlap substantially, and I look forward to a very positive panel. Christy, you want to -- anything to add to that?

Christy Anderson - *Arena Pharmaceuticals - VP of Clinical Development*
I agree with what Jack said. Obviously, we've always said that the primary focus would be on safety, and we are well prepared to thoroughly address the safety issues, or the safety data, as well as the efficacy data with the panel.

***

Alan Carr - *Needham & Company - Analyst*
Question. Wanted to follow-on one of the themes from Phil. So can you tell us what lessons you all learned from the Qnexa advisory meeting, and how that might apply to lorcaserin?

Jack Lief - *Arena Pharmaceuticals - Chairman, President, CEO*
Well remember, Qnexa was a very, very different compound than lorcaserin, and we will present much of the data, as we understand it, on lorcaserin, and I don't think we're going to have any surprises. Christy, do you want to further comment on that?

Christy Anderson - *Arena Pharmaceuticals - VP of Clinical Development*
I think -- this is going to be a recurrent theme. As we anticipated, safety was the focus of that panel, and I think we can anticipate that safety will be a key focus at the lorcaserin panel. We're doing everything in our power to be well prepared to discuss all of the safety data with the advisory panel.

***

Christy Anderson - *Arena Pharmaceuticals - VP of Clinical Development*
Again, we have always been very comfortable with the safety profile… again, I think we are pretty comfortable that we have shown a good safety and tolerability profile, and we are prepared to support that at the advisory committee.

241. Shanahan, Lief and Anderson's representations that lorcaserin, unlike Qnexa, was "safe," that "[w]e're doing everything in our power to be well prepared to discuss all of the safety data with the advisory panel," and representations about the issues the FDA and Defendants would discuss at the Advisory Committee meeting were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

242. On August 6, 2010, Arena issued a press release that stated, in part, the following:

FDA Confirms September 16th Advisory Committee Meeting to Review Lorcaserin for Obesity and Weight Management. . . .

"Our primary objective at this time is to obtain FDA approval of lorcaserin," said Jack Lief, Arena's President and Chief Executive Officer. "We have been preparing

> for this anticipated Advisory Committee meeting, and look forward to reviewing lorcaserin's profile with the panel members. . . ."

243. Lief's representations were false and misleading because he knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them.

244. On August 6, 2010, Defendants caused Arena to file a prospectus supplement pursuant to which Arena offered 8,955,244 shares of Arena common stock at a price of approximately $6.70 per share, for a total purchase price of approximately $60 million (the "August 6 Prospectus Supplement").

245. The August 6 Prospectus Supplement incorporated by reference the false statements in the 2009 10-K and the May 7, 2010 10-Q delineated above in ¶¶ 225, 227, 229, 231.

246. On August 9, 2010, Defendants caused Arena to file its quarterly report for the quarter ended June 30, 2010 with the SEC on Form 10-Q. The August 9, 2010 10-Q was signed by Lief and Hoffman and stated, in part, the following:

> An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate. . . . We submitted our NDA for lorcaserin in December 2009, and the FDA has assigned an October 22, 2010 PDUFA date for their review of our NDA
>
> ***
>
> Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin.

247. Lief and Hoffman's representations that Defendants had demonstrated lorcaserin's "long-term safety" were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors.

248. The August 9, 2010 10-Q included SOX Certifications signed by Lief and Hoffman similar to certifications in the May 12, 2008 10-Q as alleged above in ¶ 134.

249. Lief's and Hoffman's SOX Certifications were false and misleading because Defendants knew of the material facts in ¶¶ 129(i)-(viii) and intentionally or with deliberate recklessness failed to disclose them to investors in the August 9, 2010 10-Q.

> On December 22, 2010, Arena issued a press release disclosing that Defendants completed the "end-of-review" meeting with the FDA for lorcaserin that stated, in part, the following:
>
> Based on guidance we have received from the agency, we are executing several activities and expect to resubmit the lorcaserin NDA by the end of 2011. . . . The end-of-review meeting with the FDA included a discussion of the FDA's position on issues identified in the CRL and Arena's plan to respond.

250. Also on December 22, 2010, Defendants conducted a conference call with investors and research analysts to discuss the "end-of-review" meeting with the FDA, and Lief and Anderson made the following statements:

> **Christy Anderson** - *Arena Pharmaceuticals, Inc. - VP of Lorcaserin Development*
>
> Thanks, Jack. I will first summarize each of the three nonclinical topics that Jack mentioned. . . .
>
> The second nonclinical issue was an unresolved exposure response relationship for lorcaserin emergent mammary adenocarcinoma. The FDA has asked that we demonstrate the mechanism by which lorcaserin causes mammary tumors in rats and that this mechanism is reasonably irrelevant to human risk. . . . To address this issue, we have initiated nonclinical studies to provide the requested evidence to the agency.
>
> ***
>
> **Carol Werther** - *Summer Street Research - Analyst*
> So the duration of the trial is pretty short then?
>
> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President and CEO*
> Yes.
>
> ***
>
> **Jack Lief** - *Arena Pharmaceuticals, Inc. - President and CEO*
> And the agency has been very helpful in approving our protocols for the readjudication and that sort of thing. So this is all pretty clear for us.

251. These statements were false and misleading because Defendants knew of the material facts in ¶ 129(ix) and intentionally or with deliberate recklessness failed to disclose them to investors.

E. Loss Causation and Economic Loss.

252. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Arena securities and operated as a fraud or deceit on Class Period purchasers of Arena's securities. Defendants achieved this by making positive statements about lorcaserin's safety, data, and discussions with the FDA, while they knew of material negative facts and intentionally or deliberately recklessly failed to disclose them to the public.

253. Later, however, when Defendants' prior misrepresentations were disclosed and became apparent to the market, the price of Arena's securities declined precipitously as the prior artificial inflation came out of Arena's stock price. As a result of their purchases of Arena securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under the federal securities laws.

254. On September 14, 2010, the results of the Rat Study and the FDA's interest in such results were disclosed. On September 14, 2010, the price of Arena shares declined from a close on September 13, 2010 of $6.85 per share, to close at $4.13 per share, a decline of $2.72 per share or approximately 40%.

255. On September 16, 2010, trading of Arena stock was halted, pending the outcome of the Advisory Committee meeting on lorcaserin.

256. On September 17, 2010, trading in Arena shares resumed and the price of Arena's shares declined $1.75 per share to close at $1.99 per share, a decline of approximately 47% on heavy volume.

257. On January 27, 2011, Arena disclosed that Defendants learned that the FDA was interested in long-term (over 6 months) studies of lorcaserin's effects on rats.

258. In response, on January 28, 2011, the price of Arena's common stock declined $0.37 per share or approximately 19%, on heavy volume to close at $1.63 per share.

F. Fraud-on-the-Market Doctrine.

259. At all relevant times, the market for Arena's securities was an efficient market for the following reasons, among others:

(a) The Company's common stock was actively traded on the NASDAQ in a highly efficient market;

(b) As a regulated issuer, the Company filed periodic public reports with the SEC;

(c) The Company was covered regularly by securities analysts, including, among others J.P. Morgan, Oppenheimer, Rodman & Renshaw, Cowen & Co., and Canaccord;

(d) The Company regularly issued press releases which were carried by national newswires. Each of these releases was publicly available and entered the public marketplace;

(e) Defendants regularly participated in public conference calls with investors and analysts.

260. As a result, the market for the Company's securities promptly digested current information with respect to Arena from all publicly available sources and reflected such information in the price of the Company's securities. Under these circumstances, all purchasers of the Company's securities during the Class Period suffered similar injury through their purchase of the securities of Arena at artificially inflated prices and a presumption of reliance applies.

G. No Safe Harbor.

261. Defendants' false and misleading statements alleged above were assertions and statements of present or historical facts, and observed facts. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of these allegedly false statements.

262. To the extent any of the alleged false statements could be construed as forward-looking, many of these statements were not identified as "forward-looking statements" when made.

263. To the extent any of Defendants' statements are found to be forward-looking statements, there was no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

264. Indeed, as alleged herein, Defendants' cautionary language throughout the Class Period was ineffective to warn research analysts from Jefferies, J.P. Morgan, Canaccord, Cowen & Co., Rodman & Renshaw, Oppenheimer, Summer Street and Zach's of the undisclosed, material facts alleged herein.

265. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, Defendants knew that the particular forward looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Arena who knew that those statements were false when made.

FIRST CLAIM FOR RELIEF UNDER THE EXCHANGE ACT
For Violation of Section 10(b) of the Exchange Act
and Rule 10b-5 Promulgated Thereunder Against Defendants

266. Lead Plaintiff repeats and realleges each and every allegation contained above.

267. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiff and other similarly situated investors in connection with their purchases of Arena securities during the Class Period.

268. As alleged herein, Defendants acted with scienter in that they intentionally or with deliberate recklessness made statements to investors that were materially false and misleading

concerning lorcaserin. Defendants knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents.

269. The state of mind of the Individual Defendants, as well as other Arena employees acting within the scope of their employment and on behalf of Arena, and/or as Arena's agent or as agent for one or more of the Individual Defendants, such as Brunswick, is imputed to Arena. As alleged above, the Individual Defendants, as well as numerous other Arena employees, including Brunswick, knew of the Rat Study and the FDA's concerns about the Rat Study and concerns about its relevance to humans.

270. As set forth above in detail, Defendants, by virtue of their knowledge of the Rat Study, their control over, and/or receipt and/or modification of Arena's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning lorcaserin and the results of the Rat Study, participated in the fraudulent scheme alleged herein.

271. Defendants knew or at least with deliberate recklessness disregarded the false and misleading nature of their respective statements and of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of personnel at the highest level of the Company, including the Individual Defendants, and/or individuals with access to and/or received nonpublic material information concerning the results of the Rat Study and the FDA's interest in them.

272. Defendants had the motive and opportunity to perpetrate the fraudulent scheme and course of business described herein. The Individual Defendants were the most senior officers of Arena, issued statements and press releases on behalf of Arena, and each made false statements concerning lorcaserin and had the opportunity to commit the fraud alleged.

273. Defendants were motivated to inflate the price of Arena securities in order to raise over $150 million for Arena from investors from the sale of Arena common stock at artificially

inflated prices as alleged above. As alleged above, Defendants caused Arena to sell stock at suspicious times. The timing of the sales was suspicious because Defendants knew of the negative material facts alleged above, or acted with deliberate recklessness.

274. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately and recklessly disregarded as materially false and misleading in that they contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading to investors.

275. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Arena's securities. Lead Plaintiff and the Class would not have purchased Arena securities at the prices they paid, nor at all, if they had been aware that the market prices had been artificially inflated by Defendants' materially misleading statements and/or material omissions.

276. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Arena securities during the Class Period.

SECOND CLAIM FOR RELIEF UNDER THE EXCHANGE ACT

For Violation of Section 20(a) of the Exchange Act
Against the Individual Defendants

277. Lead Plaintiff repeats and realleges each and every allegation contained above.

278. Individual Defendants Lief, Shanahan, Behan, Hoffman and Anderson each acted as controlling persons of Arena within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and/or awareness of Arena's lorcaserin program, the Rat Study's results, participation in conference calls with investors and analysts and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, and attendance at meetings with the FDA on behalf of Arena, the Individual Defendants had

the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements concerning the development and safety of lorcaserin that Lead Plaintiff contends are materially false and misleading.

279. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, bi-monthly updates on the Rat Study to the FDA, drafts of, and the final Rat Study report submitted to the FDA, press releases, public filings and other statements alleged by Lead Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

280. During the Class Period, Lief and Behan were members of the Company's board of directors and had responsibilities to review, approve and monitor fundamental financial and business strategies and major corporate actions, oversee potential risks facing the Company and the Company's risk management activities, select and oversee management and determine its composition and oversee the establishment and maintenance of processes and conditions to maintain the integrity of the Company.

281. The Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and the clinical and preclinical studies of lorcaserin, and therefore, are presumed to have had the power to control or influence the materially false and misleading representations giving rise to the securities violations as alleged herein, and exercised such power.

282. As set forth above, Arena and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this complaint. By virtue of their positions as well as their conduct alleged herein, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

283. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

IV. CLASS ACTION ALLEGATIONS

284. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class of all persons and entities who purchased the securities of Arena between March 17, 2008 and January 27, 2011, inclusive (the "Class").

285. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Lead Plaintiff at the present time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are hundreds of members of the Class located throughout the United States. As of August 5, 2010, Arena had over 112 million shares of common stock outstanding.

286. Lead Plaintiff's claims are typical of the claims of the members of the Class. Lead Plaintiff and all members of the Class have sustained damages because of Defendants' unlawful activities alleged herein. Lead Plaintiff has retained counsel competent and experienced in class and securities litigation and intends to pursue this action vigorously. The interests of the Class will be fairly and adequately protected by Lead Plaintiff. Lead Plaintiff has no interests which are contrary to or in conflict with those of the Class that Lead Plaintiff seeks to represent.

287. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Lead Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

288. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) whether Defendants' misstated and/or omitted to state material facts in their public statements, press releases and filings with the SEC;

(c) whether Defendants acted with the requisite state of mind;

(d) whether Defendants participated directly or indirectly in the course of conduct complained of herein; and

(e) whether the members of the Class have sustained damages and the proper measure of such damages.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for judgment as follows: declaring this action to be a proper class action; certifying the Lead Plaintiff as a Class Representative and Lead Counsel as Class Counsel; awarding damages, including interest; awarding reasonable costs, including attorneys' fees; and such equitable/injunctive relief as the Court may deem proper.

JURY DEMAND

Lead Plaintiff demands a trial by jury.

DATED: May 13, 2013

KAPLAN FOX & KILSHEIMER LLP

By: /s/ Laurence D. King

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CERTIFICATE OF SERVICE

I, Laurence D. King, hereby declare that on May 13, 2013, I caused the foregoing to be filed electronically using the Court's CM/ECF system which sent notifications of the filing to counsel of record.

/s/ Laurence D. King
Laurence D. King